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FIRST NAMED APPLICANT

ATTORNEY DOCKET NO.

P-107,738

7/10/03

GREGORY E. AMIDON, ET AL.

01681/2

Title:

SUSTAINED-RELEASE TABLET COMPOSITION OF
PRAMIPEXOLE

Art Unit

Paper Number

Correspondence Address:

James C. Forbes

PHARMACIA CORPORATION GLOBAL PATENT DEPARTMENT

75 MARYVILLE CENTRE DRIVE

5TH FLOOR, MAIL ZONE 1006

KANSAS CITY, MO 64111

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LICENSE FOR FOREIGN FILING

[Title 35, United States Code (1952) Sections 184, 185, 186]

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Gawlik, Susan B. [LGL/1820]

From: Susie Kapeleris [skapeleris@landonstark.com]
Sent: Monday, July 14, 2003 1:15 PM
To: Gawlik, Susan B. [LGL/1820]
Subject: RE: SEE BELOW



29188.pdf

Ms. Gawlik,

Attached please find a copy of the Foreign Filing Licenses just granted. An invoice and hard copies will follow in the mail. Please contact us if you have any questions or concerns.

Thanks and Best Regards,

Susie Kapeleris
Landon Stark Cantwell & Paxton
2011 Crystal Drive - Suite 210
Arlington, VA 22202
703 486 1150
703 892 4510 (fax)
Orders & Inquiries: mail@landonstark.com
Website: www.landonstark.com or www.cantwellpaxton.com

We are pleased to announce the merger of Landon & Stark and Cantwell & Paxton

Patent Abstract

Identifying family number: 01681

Title: Sustained Release Tablet Composition of Pramipexole

Priority date: 25 July 2002

Inventors: Gregory E. Amidon, Loksidh D. Ganorkar, John M. Heimlich, Ernest J. Lee, Robert M. Noack, Joseph P. Reo, Connie J. Skoug

Originating site of invention: Kalamazoo, MI

Primary therapeutic area: Neurodegeneration

Secondary therapeutic area: Pharmaceutical Sciences

Primary claim type: Formulation

Target: Dopamine D₂ receptor (agonist)

Summary of the invention/indication:

Sustained-release tablets of a water-soluble salt of PRAMIPEXOLE comprise a hydrophilic polymer and a starch selected to have high tensile strength. The tablets exhibit improved mechanical stability and strength, resulting in improved tableting efficiency on a manufacturing scale.

Broadest coverage:

A pharmaceutical tablet comprising a water-soluble salt of PRAMIPEXOLE dispersed in a matrix comprising a hydrophilic polymer and a starch having a tensile strength of at least about 0.15 kN cm⁻² at a solid fraction representative of the tablet.

Specific embodiment:

A tablet as above comprising 0.3 to 5 mg PRAMIPEXOLE as the dihydrochloride salt. Possible MIRAPEX SR product.

Granted claims/specific issues/other relevant information:

Related to 00787, 01132, 01645.

Does this case involve a license or collaboration: No, but check Boehringer Ingelheim agreement.

Responsible agent/attorney: Jim Forbes - Skokie, IL

Outside counsel: None

United States Patent and Trademark Office

Case No. 01645/2 JCF

Inventor	Lee, et al.
Serial No.	
Reg. Date/Filing Date	July 10, 2003
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Case No. 00787/3 JCF

Inventor	Ganorkar, et al.
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Case No. 01681/2 JCF

Inventor	Amidon, et al.
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Case No. 01132/4 JCF

Inventor	Amidon, et al.
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Gawlik, Susan B. [LGL/1820]

From: Chris Robbins
Sent: Thursday, July 10, 2003 1:36 PM
To: Gawlik, Susan B. [LGL/1820]
Subject: RE: 00787/3, 01132/4, 01645/2, 01681/2

Dear Ms. Gawlik,

Please note that our name and address have changed—see new contact information below. We received your four expedited license applications, and we have delivered them to the Office of Licensing & Review. Attached please find the stamped receipt post cards. As soon as the licenses are issued, we will email them to you. Hard copies will be delivered via regular mail. Please contact us if you have any questions.

Regards,

Chris Robbins
Senior Researcher
Landon Stark Cantwell & Paxton
2011 Crystal Drive - Suite 210
Arlington, VA 22202
703 486 1150
703 892 4510 (Fax)
Orders & Inquiries: mail@landonstark.com
Website: www.landonstark.com or www.cantwellpaxton.com

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01681/2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Amidon, et al) ATTORNEY DOCKET NO.: 01681/2
SERIAL NO.: n/a) GROUP ART UNIT: n/a
FILED: n/a) EXAMINER: n/a
TITLE: SUSTAINED-RELEASE TABLET COMPOSITION OF PRAMIPEXOLE
DATE: July 10, 2003

Assistant Commissioner for Patents
Washington, DC 20231
Attention: Security Group 220, Licensing and Review

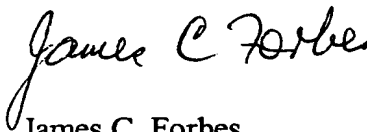
Sir:

PETITION FOR EXPEDITED LICENSE FOR FOREIGN EXPORTING AND FILING
UNDER 37 CFR §5.12(b)

Applicant hereby petitions for a license for foreign exporting and filing for subject matter related to the patent application referenced above. **THIS SUBJECT MATTER IS RELATED TO PHARMACEUTICAL COMPOSITIONS AND IS CLEARLY OF NO CONCERN FROM A SECURITY STANDPOINT.**

- [X] Additional related U.S. applications are identified on the enclosed sheet.
[X] Applicant further petitions for expedited handling of this license.
[X] Please charge the sum of \$130, or such greater or lesser amount as may be required under 37 CFR §5.12(b) and §1.17(h), to Deposit Account No. 19-1025.

Respectfully submitted,



James C. Forbes
Agent for Applicant
Registration No. 39,457
Tel. (847) 581-6090

Address correspondence to:

Pharmacia Corporation
Global Patent Department
575 Maryville Centre Drive
5th Floor, Mail Zone 1006
St Louis, MO 63141

Encl: Additional related U.S. application information
Triplicate petition
Subject matter/patent application for which license is sought

01681/2

PETITION FOR EXPEDITED LICENSE FOR FOREIGN EXPORTING AND FILING
UNDER 37 CFR §5.12(b)

ADDITIONAL RELATED U.S. APPLICATION INFORMATION

<u>Serial No.</u>	<u>Filing date</u>	<u>Pending/abandoned</u>
60/398,427	July 25, 2002	Pending
60/398,447	July 25, 2002	Pending
U.S. Provisional Application titled "Sustained-release tablet composition of pramipexole" by G.E. Amidon et al., filed June 18, 2003, attorney docket no. 01681/1/US (no serial no. available)		

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